



CTSUS Quarterly Newsletter

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Note from the CTSUS Project Director

By Steve RIORDAN

The news from the CTSUS is that the sharp upward trend in accrual noticed at the end of last quarter continues. For the foreseeable future, we expect to enroll more than 600 patients each month. This speaks well to the popularity of the Cooperative Group trials on the CTSUS menu.

This fall, three new trials will be opening which will use the CTSUS RDC system: ACOSOG Z4032, ACOSOG Z1031, and ECOG TAILORx. The Z4032 trial (lung cancer) has already been activated, but only to ACOSOG membership. Z1031 (breast cancer) should be activated in October, to both ACOSOG and CTSUS membership. Data management and RDC training for both will be provided by the CTSUS.

As many of you know, the accrual target for ECOG TAILORx is quite large and this study should be opened at many sites. The activation date should be in November, so please watch the bi-monthly broadcasts and our web site for more information.

Please remember to take advantage of the redesigned RSS page on the CTSUS web site (<http://members.ctsu.org>). This was described in the last newsletter and

will aid you in finding more information about your site. The Drug Safety Notification page, also described in a recent article, has been very popular based on the number of web site hits. Any further feedback on these new features of the web site would be welcomed.

Comments may be sent to CTSUSContact@Westat.com.

Have an enjoyable fall!

CTSUS Trivia

Question: To which Group's trials have CTSUS Sites enrolled the most patients?



Answer: NCIC-CTG. NCIC-led trials have had the highest total accrual of any Group trials on the CTSUS menu.

New Question: Approximately how many IRB approvals are processed by the CTSUS Central Regulatory Office each month?

Answer: Next issue

Feedback?
Comments?
Contact Us!

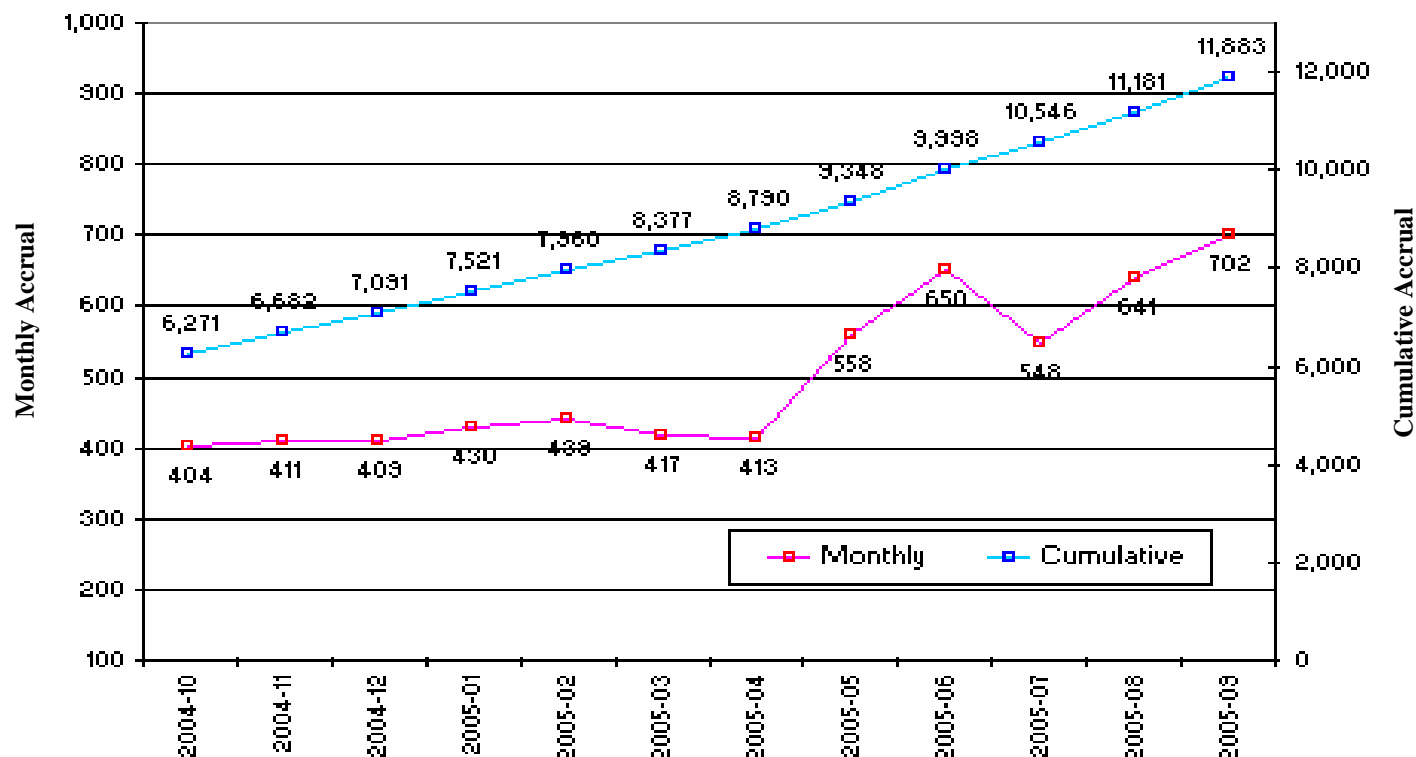


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CTSU Accrual Summary

CTSU Accrual Summary
September 30, 2005



Just Opened on the CTSU Menu!

By *Lena MUWAKKI*

Protocol #: ECOG 2603

Title: A Randomized, Placebo-Controlled Phase III Trial of Carboplatin, Paclitaxel and BAY 43-9006 versus Carboplatin, Paclitaxel and Placebo in Patients with Unresectable Locally Advanced or Stage IV Melanoma

Accrual Target: 800

Endorsing Groups: CALGB, SWOG

ECOG Activation Date: 6/23/05

CTSU Activation Date: 7/8/05

Protocol #: ECOG 5202

Title: A Randomized Phase III Study Comparing 5-FU Leucovorin and Oxaliplatin versus 5-FU, Leucovorin, Oxaliplatin and Bevacizumab in Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular Markers

Accrual Target: 3438

Endorsing Groups: CALGB, NCCTG

ECOG Activation Date: 8/4/05

CTSU Activation Date: 8/8/05

Protocol #: CALGB 80405

Title: A Phase III Trial of Irinotecan/5-FU/Leucovorin or Oxaliplatin/5-FU/Leucovorin with Bevacizumab, or Cetuximab (C225), or with the Combination of Bevacizumab and Cetuximab for Patients with Untreated Metastatic Adenocarcinoma of the Colon or Rectum

Accrual Target: 3450

Endorsing Groups: NCCTG, SWOG

CALGB Activation Date: 9/15/05

CTSU Activation Date: 9/22/05

Top 10 Reminders from the CTSU Help Desk

By Doug BUSHNELL

We decided to have our own Top Ten List! We took the top ten categories for Help Desk calls and came up with these friendly reminders!

1. **Site Registrations-Part 1:**

When you have submitted a protocol approval request for your site, allow 72 hours to pass and then check your site listing for approval on the CTSU Members web site under the RSS tab.

2. **CTSU Members Web Site**

Access: To obtain a username and password for the CTSU Members web site, go to the CTSU Public web site at www.ctsu.org and look on the left-hand column where it says "Register." Once you get to the CTEP web page select "New Registration" and fill in the blanks. The membership process takes approximately 48 hours.

3. **CTSU Web Site Navigation:**

One suggestion is to occasionally look over the CTSU Members web site; we are updating the web site all the time. If something is new, we try to make that as obvious as possible, so that you can take a look at the new section. By reviewing the web site every now and then, you can ease the stress during those patient waiting times.

4. **Web Site Document Access:**

When accessing protocol documents on the CTSU Members web

site, please remember that some of the files are quite large, so the fewer programs you have open at that time the better. Some protocols are more than 150 pages, so they need quite a bit of memory to be accessed.

5. CTSU Processes: The CTSU Process Checklist can save you a lot of time in the site registration and patient enrollment processes. The CTSU Process Checklist is located on the CTSU Members web site under the "Protocols" Tab on the right hand side under the title "Information Pages." On the Public Site for CTSU, the Process Checklist is located on the left-hand column under the "Guides and Training" heading.

6. **Site Registrations- Part 2:**

When faxing documents to the Regulatory Office for site registration, keep the confirmation sheet from the fax machine and make it part of the protocol file. If necessary, the confirmation sheet can be used in the recall of previously sent faxes.

7. **Drug Distribution Process:**

Whenever you call the Help Desk with drug delivery questions, it would be handy to have the patient ID number and your site code on hand.

8. CTSU Members Web Site Annual Renewal Process: The CTSU Members web site is set up on an

annual renewal basis. If you try to access the Members web site and you cannot log in, one possibility is that your username and password need to be confirmed and renewed. All you have to do is go to the Members area of the CTEP web site, review your account information to make sure it is up to date and then submit it. Once you go back to the CTSU Members web site you should be able to sign back in.

9. CTSU Active Status: A site is a CTSU member based on the physicians within the organization, not the site CTSU status. If the physician is CTSU active, then the site is CTSU active as well.

10. **Request for Site ID Code:**

If you are calling the Help Desk for a site ID code, have the zip code for the institution you are inquiring about. The easiest way to search for a site is by the zip code, not by the name. And don't forget, you can always get your site code by checking under the RSS tab on the Members web site.



Data Submission Reminder!

Reminder - Please be sure to COPY CRFs BEFORE you send off the package to the CTSU. Please make this part of your routine form submission process.

TAILORx Trial to Utilize Remote Data Capture

By Jenny HOPKINS

ECOG's Program for the Assessment of Clinical Cancer Tests (PACCT-1), also known as the Trial for Assigning Individualized Options for Treatment (TAILORx) is expected to be activated by ECOG and the CTSU during the month of November. This breast trial is slated to register/screen over 10,000 patients and randomize over 4,000, and has been heavily endorsed through the CTSU. Through collaboration between ECOG, the NCI and the CTSU, sites will be able to submit data for this trial to the CTSU via Oracle Clinical Remote Data Capture (OC-RDC) as part of a continuing pilot program assessing the use of

RDC in Cooperative Group clinical trials. ECOG and the CTSU are working together to come up with a number of sites that are well-suited to use RDC for this study.

In order to accommodate the number of people that will be undergoing RDC training for this and other trials, the CTSU has created a schedule of training classes via webcast technology (you can do the training right from your desktop), as well as an on-line training registration process that should be simple and seamless for users. All training registration will be handled through the CTSU Members web site at <http://members.ctsu.org> (password required), under the

RDC tab. NOTE: If you are already certified to use OC-RDC Version 4.5 Classic (i.e. because of participation in N0147) you do not need to repeat the training. You will, however, need to contact the CTSU Help Desk (1-888-823-5923 or ctsucontact@westat.com) to get your privileges updated to include TAILORx once your site is approved to conduct the trial).

Please continue to check the CTSU Bi-Monthly and the CTSU web site for updates on the TAILORx trial and RDC.

Meet the TAILORx Team

By Karen MARTIER

In anticipation for the activation of the TAILORx study, I would like to take this opportunity to introduce the TAILORx CTSU data management team. Our start up team will consist of a clinical data manager and a senior data research associate, and will operate out of the CTSU-Houston office. With an expected accrual rate of over 300 patients a month for three years, we anticipate this study to generate a high volume of data management activity starting in 2006. Already, though, the team is busy working with ECOG to prepare for implementing this very important adjuvant breast cancer study.

The clinical data manager is Ginger Riley. Ginger has worked on the CTSU for 18 months and has played a key role in the NCCTG

N0147 RDC (Remote Data Capture) pilot program. She has four years of clinical research experience across the data management, regulatory, and clinical monitoring activities. Ginger was instrumental in establishing and implementing RDC procedures for the N0147 study and, since the TAILORx study will utilize RDC, Ginger's expertise in this area will be quite handy.

Supporting Ginger is Kim Yuen. Kim is a senior data research associate with two years of data management experience. She has worked on a number of clinical research studies including the NCIC-CTG BR.19 and MA.27 studies, and the ACOSOG Z4032 study. Kim has experience in database development and data cleaning activi-

ties, and will play a key role in these areas on the TAILORx study.

The manager of the TAILORx team is Whitney Smith. Whitney has seven years of data management experience across a large variety of therapeutic areas. Among other responsibilities, she manages the data management operations of the CTSU-Houston office and has worked on the ACOSOG Z0432 and Z1031 studies, and now the TAILORx study. Whitney will provide oversight and guidance to the team. Together, Ginger, Kim, and Whitney form a strong and dedicated team as we move forward with this study.

Federal Wide Assurance Numbers *By Martha HERING*

The Office of Human Research Protection (OHRP) has directed all institutions that currently hold Cooperative and Multiple project assurance numbers to update to a Federal Wide Assurance (FWA) by 12/31/2005. While most institutions participating in Cooperative Group trials have already updated to an FWA, the documentation of the update may not have been provided to the Regulatory Support System (RSS). To help facilitate collection across the Cooperative Groups, the CTSU Regulatory Office will collect and enter updated assurance numbers in RSS and share this data with the Cooperative Groups. Please complete the following steps:

1. Check the assurance number currently on file in RSS by accessing the CTSU Members web site RSS tab. Expand the browser tree to view your associated institutions, and select the institution. The assurance number is included in the institution summary on the right.
2. If your site has a current FWA but it is not listed RSS, fax a copy of the OHRP web page printout, or a copy of the OHRP notification of your site's assurance to the CTSU Regulatory Office with the CTSU Regulatory Transmittal Sheet.

3. The OHRP printout is available at <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR>. Search options by location, institution or assurance number are available (see screen shot below). Once you have found your institution's record select the <detail> link on the right, and print the detail page.

4. Please include all applicable NCI CTEP ID(s) covered under the FWA on the printout or memo. Updates will not be made if the NCI CTEP ID is not on the form.

5. If your site does not yet hold an FWA, please file with OHRP as soon as possible at http://www.hhs.gov/ohrp/assurances/assurances_index.html. **HINT:** File electronically

6. Upon receipt of your institution's FWA, please fax the assurance information to the CTSU Regulatory Office, following steps 2 through 4 above, remembering to include your institution's NCI CTEP ID.

As of Jan. 1st, 2006 institutions that do not have a FWA on file will be considered non-compliant and may have enrollment privileges suspended.

